

RD General Agenda Topics – June 15, 2021

Briefings for Michal

- PRIA/registration overview 2/23rd (complete)
- Dicamba 2/18th (complete)
- Sulfoxaflor 3/4th (complete)
- Pet incidents 3/31st (complete)
- FDA/EPA jurisdiction 4/12th (complete)
- SW2 revocation options 5/3rd (complete)
- Antibiotics 5/17th (complete)

New Active Ingredients (include original PRIA date)

- Tetraniliprole – completed!
- Broflanilide – completed!
- Picarbutrazox – completed!
- Fluxametamide – completed!
- Fluindapyr – completed!
- Trifludimoxazin – completed!
- Rekleml – PD being developed. PRIA date **7/19/21** (Original PRIA date 4/19/21) (IVB3). Partial ESA – causing delays
- Ipflufenquin – PD being developed. PRIA date **7/30/31** (Original PRIA date 4/19/21) (FB). Working on ESA – with the OPP-IO
- L-Glufosinate Ammonium – Risk Assessment phase. PRIA date 10/12/2021 (FHB). ESA issue. Briefing Ed on ESA and resource considerations in June

Other Chemical Actions

- Dicamba
 - ~~Bayer and BASF requesting feedback on pending pre-mixes~~

Ex. 5 Deliberative Process (DP)

- **USDA conducting EIS** (instead of EA) on dicamba resistant corn; issued a 60-day public comment period 5/8th; citing EPA's cancellation order and 2020 decision. Discussed with OPMP. Comment period extended to 6/28. Coordinating with AO's OP and regions; OPP team recommends not sending substantive comments at this point
- **24 (c)s** –
 - NC – denial 3/15th
 - TN – denial 4/9th
 - GA – denial 4/23rd
 - **TX – Notice of intent to deny NLT 6/18th; denial NLT 6/30th – draft NOID with AO for signature**
 - **GA – Tavium request; heads up from Syngenta**
- **Antibiotics** – will need to brief the new team (FB)

- Briefed Michal 5/17th; Received policy feedback on the antibiotic issue; Oxytet – cherry PRIA date of June – delay the action while we work on policy approach.
- **Inorganic Bromide** – R10 meeting with OPP; APHIS meeting with Michal – requesting increase in tolerance on alfalfa (Dan R)
- **Cyclanilprole/flonicamid** – first residential use; public process; published proposal!
- **Seresto** – pet collar with high rate of incidents (death and neuro); press inquiries; 6a2 letter sent; updated desk statement to include factual information on FDA vs. EPA; received information from Elanco; team is developing a schedule
- **Ex. 5 Deliberative Process (DP)**
- **Enlist** – Extension of the registration (expires end of 2021); Corteva is looking for a decision to inform seed purchase for soybeans; OGC advises an to update ESA finding

Other Actions - AA-Level/OD/High Visibility Items

- FDA/EPA jurisdiction – Michal follow up complete; team identified appropriate “model” MOUs and sent talking points; Ed is reaching out
- COVID-19 Activities – Sect 18s –
 - SW2 –
 - revocation of existing AR, TX S18s based on science and violations (week of June 23rd) –

Ex. 5 Deliberative Process (DP)

- Grignard – reviews complete; working on authorization letters – meeting with Grignard to express concerns about promotional materials (NV, PA, TX, MD; amendment to TN and GA)
- Kraton – completed!
- Ionopure Air – risk issues
- Acteev Facemasks
- **OIG Audits**
 - dicamba/science integrity report coming soon – desk statement; meeting with Janet on unresolved recommendation.
 - MP3 oversight – corrective action on recommendation 5 (revise NPMG guidance) due in June 30, 2021; Revising per Mike’s comments
 - 24c audit – corrective action on recommendation 5 (contact state partners on pre-submission consultation options) due June 2021
- **PFAS** – RD working with Clark on submissions
 - Definition issue – working to bring Jeff D. up to speed
 - 6a2 notification? Nothing planned yet
- **Inerts** supply issue – phase 1 completed!; phase 2 – Revised response per comments
- **Inert** – Fragrance petition (Pat Quinn) – 2 petition responses scheduled for OGC review in June (Kerry); other petition responses will follow within existing resource constraints
- **CRP** (Child resistant Packaging) testing – industry has requested flexibilities in testing requirements due to COVID impacts; CPSC (whose regulations we use) have issued similar

flexibilities. Team recommends issuing some but not all flexibilities. Next steps- COVID workgroup

- **IST – Incident Screening Team**

International

- Bi-monthly meeting with PMRA 5/11th – antibiotics, Seresto – complete; next meeting July
- PMRA – industry JR meeting 6/29th
- WPP meeting – 7/2nd

Business/process/technology

- ISB – FEP/21-day backlog:
 - backlog addressed by end of April; RD SWAT team addressing newer receipts
 - Working to complete RD SWAT actions
- eCSF/OPPEL – eCSF May 9th soft launch; OPPEL -TBD
- MRL – structured data for OPP and share with FDA; FDA is applying for internal grant – supports OPP digital transformation; OPP serving as reviewer

Speaking Engagements –

Ex. 5 Deliberative Process (DP)

CA topics (Karen Morrison):

- Missing environmental hazard statements – RD BC's are generating a response